Proposed Rule – Tobacco Products Deemed to be Subject to the Food, Drug, & Cosmetic Act ("Deeming Rule")

Center for Tobacco Products

U.S. Food and Drug Administration

10:00 AM- May 29, 2014

Provide Questions and Comments to the Formal Docket

- A transcript of this webinar will be placed in the docket. CTP also requests participants to submit comments to Docket Number FDA-2014-N-0189

Agenda

- Background and need for proposed rule
- “Deeming” provision
- Public health benefits from automatic provisions associated with deeming
- Additional restrictions for covered tobacco products
- Key issues
  - “Premium cigars”
  - E-cigarettes
  - Premarket Review of newly deemed tobacco products
- Questions & Answers

Background

- Tobacco Control Act (TCA) gave FDA immediate authority over certain tobacco products
- Section 901 authority
- Section 906(d) authority

Need for Proposed Rule

- Highly substitutable products
- Compelling evidence regarding health risks and misperceptions about the safety of currently unregulated products
- Continuing development of newer, novel tobacco products that contain nicotine (an addictive chemical) and unknown levels of toxicants
- Many of these novel product may also appeal to youth

Summary of the Proposed Rule

Two-part rule:

1. "Deeming" provision
   - Preamble describes significant benefits
2. Additional restrictions
   - Scientific evidence shows that they are appropriate for the protection of the public health

“Deeming” Provision

- “Deeming” provision
  - Option 1 -Would apply to all products meeting the statutory definition of “tobacco product,” i.e., any product “made or derived from tobacco” that is not a “drug,” “device,” or “combination product” (except for accessories of deemed tobacco products)
    - Examples: hookah, e-cigarettes, cigars, pipe tobacco, novel tobacco products, and tobacco products that may be developed in the future
  - Option 2 – Same as Option 1 but would excludes “premium” cigars

“Deeming” Provision (continued)

- Automatic provisions: provisions in the FD&C Act that generally apply to “tobacco products” would then be extended to and automatically apply to newly deemed tobacco products
  - Examples: registration, product and ingredient listing, user fees for certain products, premarket requirements, adulteration and misbranding
- Other FD&C Act authorities may be invoked in future regulations, such as establishment of Tobacco Product Manufacturing Practices (TPMPs)

Public Health Benefits from Automatic Provisions

- Prohibit adulteration and misbranding
- Requirement for ingredient listing
- Requirement for registration and product listing
- Review of substantial equivalence (SE) filings and premarket applications (PMTA) for newly deemed products
- Elimination of misleading descriptors and unproven modified risk claims
- Prohibition of free samples

Additional Restrictions for Proposed Covered Tobacco Products

1. Prohibit sale to individuals under the age of 18 years and require age verification
2. Prohibit sale using electronic or mechanical devices, e.g., vending machines, with limited exception
3. Require the display of health warnings
   - Would apply to “covered tobacco products” - deemed products except for components or parts that do not contain nicotine or tobacco

Health Warnings

- Would require display on covered tobacco product packages and in advertisements
  - Product package: 2 principal display panels (PDP); warning area shall comprise 30% of each PDP
  - Advertisement: occupy at least 20% of the area of the ad
  - Requirements the same as for smokeless tobacco

Health warning for all covered tobacco products

- **"WARNING**: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."
- Self-certification option: would allow a manufacturer to submit a confirmation statement to FDA certifying that its product does not contain nicotine and that the manufacturer has data to support that assertion.
  - Instead of addiction warning, the product would be required to bear the statement, "This product is derived from tobacco."

Additional Health Warnings for Cigars

- Four warnings identical to Federal Trade Commission consent agreements (2000):
  - **WARNING:** Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
  - **WARNING:** Cigar smoking can cause lung cancer and heart disease.
  - **WARNING:** Cigars are not a safe alternative to cigarettes.
  - **WARNING:** Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- Special rule for cigars sold individually and not in product package

Effective Dates Would Vary by Provision

- Generally: the rule would be effective on the final rule publication date plus 30 days
- Would apply to deeming provision and associated automatic provisions, age restriction, and prohibition on vending machine sales
- Proposed compliance dates for certain automatic provisions using existing dates in TCA as guide
- For example, proposing 24 month compliance period for substantial equivalence (SE) and premarket tobacco applications (PMTA)
- Addiction health warning and four health warnings for cigars: publication date plus 24 months to stop manufacturing; publication date plus 25 months to stop distributing

Key Issue: Premium Cigars

- Significant interest in whether premium cigars should be deemed
- Rule proposes two options:
  - Option 1 - extend FDA's authority to all products that meet the statutory definition of a tobacco product (except accessories).
  - Option 2 – Same as Option 1, but would exclude premium cigars

Key Issue: Premium Cigars (continued)

- Option 2:
- Proposed definition of cigar: means a tobacco product that:
- (1) Is not a cigarette and
- (2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco

Key Issue: Premium Cigars (continued)

- Proposed definition of covered cigar: any cigar as defined in this part, except a cigar that:

(1) Is wrapped in whole tobacco leaf;

(2) Contains a 100 percent leaf tobacco binder;

(3) Contains primarily long filler tobacco;

(4) Is made by combining manually the wrapper, filler, and binder;

(5) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;

(6) Has a retail price (after any discounts or coupons) of no less than ten dollars per cigar;

(7) Does not have a characterizing flavor other than tobacco; and

(8) Weighs more than six pounds per thousand units.

Key Issue: Premium Cigars (continued)

- Requests comments:
  - Whether all cigars should be subject to deeming
  - What other provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars

Key Issue: E-Cigarettes

- FDA cannot use its “tobacco product” authorities to regulate e-cigarettes and other “customarily marketed” tobacco products until deeming rule is finalized
- Research still in early stages but concerns exist, particularly about youth use
- Products contain nicotine, varies among brands (some are mislabeled)
- Contain variable levels of carcinogens and toxicants
- Mistaken consumer perceptions regarding safety

Key Issue: Premarket Review of Newly Deemed Tobacco Products

- Once deemed, a "new tobacco product" is subject to premarket review requirements
  - Would affect those currently on the market and those trying to enter the market
- "New tobacco product" = not commercially marketed in the U.S. as of 2/15/2007
  - Express "grandfather date" is found in the TCA; FDA believes this is not subject to change but requests comment

Premarket Review of Newly Deemed Tobacco Products (continued)

- 3 pathways to marketing “new” tobacco products:
  1) Premarket tobacco application (PMTA);
  2) Substantial equivalence (SE) report; and
  3) SE exemption

Premarket Review of Newly Deemed Tobacco Products (continued)

- Predicate tobacco product (comparison product)
  - Commercially marketed in the U.S. as of 2/15/07 or has been previously determined to be SE
- Proposed compliance date for SE and PMTA submissions: effective date of the final rule plus 24 months

Premarket Review of Newly Deemed Tobacco Products (continued)

- *But…*FDA believes the SE pathway may not be available for some newly deemed tobacco products
  - Inability to identify viable predicate that was on the market as of 2/15/2007
- Having only the PMTA pathway could impact manufacturers, such as e-cigarette firms
- Preamble asks a series of questions to elicit comment on other regulatory approaches FDA may consider, e.g., expediting review of PMTAs

NPRM requests comment

- Compliance periods for market pathways
- Compliance dates for automatic provisions
- Predicate date for SE products
- Health warning statements
- Premium cigars
- E-cigarettes
- Components, parts, and accessories